



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

November 26, 2021

Keith Mullen, CIH, CSP
Radiation Safety Officer
Enbridge Pipeline (Lakehead), LLC
11 E Superior St., Ste. 125
Duluth, MN 55802

Dear Mr. Mullen:

This letter is in reference to the application dated July 27, 2021, signed by Bob Lehto, Area Manager, requesting the renewal of U.S. Nuclear Regulatory Commission (NRC) Materials License No. 22-35063-01.

The NRC's guidance document for your type of license, which I refer to throughout this letter as "the guidance", is NUREG-1556, Volume 4, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Fixed Gauge Licenses." The latest revision was published on July 2016 and is accessible at: <https://www.nrc.gov/docs/ML1618/ML16188A048.pdf>

Upon review of your application, I identified the following areas requiring additional or clarifying information:

1. Section 8.3, "Item 3: Address(es) Where Licensed Material Will Be Used or Possessed," specifies that you must provide the address for each facility where you will receive, use or store licensed radioactive material.

The application omitted your licensed facility in Dansville, Michigan. Clarify the status of this licensed facility.

If applicable, please provide the following information in support of the request to remove this facility from your license:

- Submit records of transfer and/or disposal for all sealed sources or fixed gauging devices previously used or stored at the former location. If transferred outside of your organization, please provide a copy of the transferee's license and a letter confirming receipt of the transferred fixed gauging devices.
- Submit current Leak Test Reports for all sealed sources or fixed gauging devices previously stored at the former location.
- Describe any incidents involving ruptured, leaking or lost sealed sources or fixed gauging devices along with any other incidents involving radioactive materials at the former licensed facility.

2. Section 8.7.1, "Radiation Safety Officer," of the guidance identifies that the Radiation Safety Officer (RSO), is responsible for the oversight of licensed operations. The RSO must have sufficient organizational authority and management prerogative to enforce appropriate radiation protection rules, standards, and practices.

To formally establish the organizational authority of your office, please submit a current Delegation of Authority signed by a management representative. A model Delegation of Authority is provided in Appendix C, "Typical Duties and Responsibilities of the Radiation Safety Officer," of the guidance.

3. Section 8.5.1. "Sealed Sources and Devices," and Section 8.6, "Item 6: Purpose(s) for Which Licensed Material Will Be Used," of the guidance states that applicants must provide information regarding the radioactive material requested and the intended purpose of use. This should include the following:
 - identification of each radionuclide and nominal activity for each fixed gauging device;
 - identify the manufacturer (or distributor) and model number of each type of fixed gauging device;
 - state the number of each type of fixed gauging device requested;
 - provide a description of the use of the fixed gauging devices; and
 - list the activity per source and the maximum activity per fixed gauging device being requested, which must not exceed the maximum activity listed in the approved certificate of registration issued by the NRC or by an Agreement State.

Your application did not provide all required information. Further, the total licensed activity varies from that presently authorized in your license.

Please resubmit your application providing complete information for Items 5 and 6, "Materials To Be Possessed and Proposed Uses." Identify all requested radionuclides and specify the activity per source and the total activity for each type of fixed gauging device in your possession.

4. Section 8.9, "Item 9: Facilities and Equipment," of the guidance describes the regulations and criteria for facilities and equipment.

In your application, you stated the following: "We will ensure that the location of each fixed gauge meets the criteria in Section 8.9, 'Facilities and Equipment,' in NUREG-1556, Volume 4, Revision 1, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Fixed Gauge Licenses.'"

Though, this statement was provided in reference to Item 8.8, "Item 8: Training for Individuals Working in or Frequenting Restricted Areas."

To ensure clarity regarding the commitment made, please revise your response removing the reference to "Training for Individuals Working in or Frequenting Restricted Areas," and replacing it with what appears to be your intended reference to Item 8.9, "Item 9: Facilities and Equipment."

5. Section 8.10.3, "Material Receipt and Accountability," of the guidance, identifies that licensed material must be tracked "from cradle to grave" in order to ensure gauge accountability; identify when sealed sources/gauges could be lost, stolen, or misplaced; and ensure that possession limits listed on the license are not exceeded. Licensees must do the following:

- Maintain records of receipt, transfer and disposal of fixed gauging devices;
- Conduct physical inventories every 6 months (or at other intervals justified by the applicant and approved by the NRC) to account for all sealed sources; and
- Update transactions in the National Source Tracking System (NSTS) and perform an NSTS annual inventory reconciliation, if applicable.

The "Response from Applicant," section of the guidance, specifies that the following responses may be provided:

- The statement, "Physical inventories will be conducted every 6 months or at other intervals approved by the NRC to account for all sealed sources and devices received and possessed under the license"; or
- A description and justification of an alternate frequency and/or procedure to account for all sealed sources and devices received and possessed under the license; and
- The statement, "We will develop, implement and maintain procedures for ensuring accountability of licensed materials at all times."

In your application, you stated the following: "Physical inventories will be conducted every 6 months or at other intervals approved by the NRC to account for all sealed sources and devices received and possessed under the license."

Your response is not complete because your response does not also identify how you ensure accountability of licensed materials at all times. Please provide a complete and acceptable response.

6. Section 8.10.6, "Operating, Emergency, and Security Procedures," of the guidance, states that applicants must develop, implement and maintain adequate Operating, Emergency & Security (OE&S) Procedures. In addition, copies of the OE&S Procedures must be provided to all gauge users and the procedures should be posted or otherwise made available at each location of use.

In your application, you stated the following: "Operating, emergency, and security procedures will be developed, implemented, maintained, and distributed, and will meet the criteria in Section 8.10.6, 'Operating, Emergency, and Security Procedures' in NUREG-1556, 8-26 Volume 4, Revision 1, 'Consolidated Guidance About Materials Licenses: Program- Specific Guidance About Fixed Gauge Licenses.'"

Your response appears to include a reference to page 8-26 of the guidance. This appears to be a typographical error. To ensure clarity regarding the commitment made, please revise your response removing the reference to page 8-26 of the guidance.

7. Section 8.10.8, "Maintenance," of the guidance identifies that licensees should routinely clean and maintain gauges according to the manufacturer's or distributor's written recommendations and instructions. Though, specific authorization by the NRC or an Agreement State is required to perform nonroutine maintenance and repair of fixed gauges.

The "Response from Applicant," section of the guidance, specifies that the following responses may be provided:

For routine maintenance, submit one of the following:

- the statement: "We will implement and maintain procedures for routine maintenance of our gauges according to each manufacturer's or distributor's written recommendations"; or
- alternative procedures for NRC review

For nonroutine operations, submit one of the following:

- the statement: "The gauge manufacturer, distributor, or other person licensed by the NRC or an Agreement State will perform nonroutine operations such as installation, initial radiation survey, repair and maintenance of radiological safety components, relocation, replacement, alignment, removal from service, and disposal of sealed sources"; or
- a request to perform this work "in-house," using the information in Appendix J of this NUREG to support the request.

Your application states, "We will implement and maintain procedures for routine maintenance of our gauges according to each manufacturer's or distributor's written recommendations and instructions." This is not a complete response as it does not address nonroutine operations.

Please revise and resubmit your application providing a complete response. You may refer to Section 8.10.8 and Appendix J, "Information Needed to Support Applicant's Request to Perform Nonroutine Operations," of the guidance for additional information.

In accordance with 10 CFR §2.390 of the NRC's "Rules of Practice," a copy of this letter will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <https://www.nrc.gov/reading-rm/adams.html>.

To continue review of your application, I request that you submit your response to this letter within 30 calendar days from the date of this letter. In your response, please refer to the license, docket, and control number specified below. I will assume that you do not wish to further pursue this licensing action if I do not receive a reply within the specified timeframe noted above.

If you have questions, require additional time to respond, or require clarification on any of the information stated above, I encourage you to contact me at Jason.Kelly@nrc.gov or at (630) 829-9737.

Sincerely,

Jason M. Kelly, MPH
Health Physicist
Materials Licensing Branch

Docket No.: 030-38641
License No.: 22-35063-01
Control No.: 627429